APR 19 2011

510(k) SUMMARY

K110148

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Part 807.92.

Submitter's Name: Microsurgical Laboratories, dba Wexler Surgical Supplies
11333 Chimney Rock Road, Suite 110
Houston, TX 77035
Telephone: (713) 723-6900
Fax: (713) 723-6906
Contact person: Mr. Danny Fishman, COO

Date of Summary: January 13, 2011

Device Names:
Trade Name, Common Name: Vascular Clamps, various
Classification Name: Vascular Clamp (21 CFR 870.4450, Product Code DXC)

Legally Marketed Device to which Equivalence is Claimed: The legally marketed predicate device is the Vascular Clamp (K072834) manufactured by Surgical Instruments Belgium (SIBEL) SA, determined to be substantially equivalent to a legally marketed (preAmendment) device on January 9, 2008.

Device Description: The Wexler Vascular Clamp Series is a family of vascular clamps, both stainless steel and titanium alloy, used during surgical procedures. The clips are supplied non-sterile and are chosen based on the dimensions, features and technological characteristics desired.

Intended Use: The Wexler Vascular Clamp Series is indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.

Descriptive Summary of Technological Characteristics and Those of Predicate Device: The indications for use, principles of operation, and device design of the Wexler Vascular Clamp Series are virtually identical to those of the predicate device, the Vascular Clamp (K072834) manufactured by Surgical Instruments Belgium (SIBEL) SA. Both series of devices are made of stainless steel or titanium, and share technological characteristics common to all vascular clamps of their types. These devices function by clamping around the blood vessel, and the degree of closure is adjusted by a ratcheting handle. There are no significant differences in either technology or performance specifications. The Wexler Vascular Clamp Series devices are supplied non-sterile, and the devices are subjected by the user to the sterilization cycle specified by the institution.

Conclusion: The information and data provided in this 510(k) Notification establish that the Wexler Vascular Clamp Series is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wexler Surgical Supplies, Inc.
c/o Devices for the Future
540 College St.
Bellaire, TX 77401
Attn: Lisa S. Jones

APR 19 2011

Re: K110148
Trade/Device Name: Wexler Surgical Vascular Clamp Series
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: April 5, 2011
Received: April 6, 2011

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110148

Device Name: Wexler Vascular Clamp Series

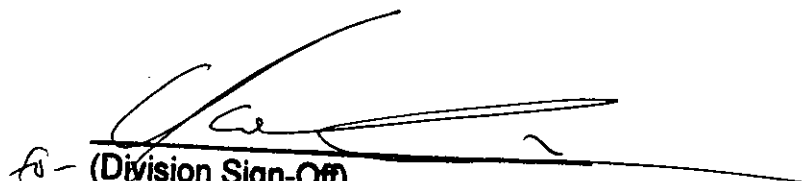
Indications For Use: The Wexler Vascular Clamp Series is indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110148